UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. DAKOTA LABORATORIES, LLC, a limited liability company, and CHARLES L. VOELLINGER, SR., an individual, Defendants.	)	Civil No. 13-4086

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents that:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin Dakota Laboratories, LLC, a limited liability company, and Charles L. Voellinger, Sr, an individual (collectively "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) because they have been manufactured, processed, packed, and held under conditions that do not comply with Current Good Manufacturing Practice ("CGMP") requirements; and (b) violating 21 U.S.C. § 331(k) by causing drugs to be adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) after shipment of one or more of their components in interstate commerce.

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and 1391(c).

Defendants

4. Dakota Laboratories, LLC, is a South Dakota limited liability company that manufactures, processes, packs, labels, holds, and distributes drugs. Its facilities are located at 1022 North Main Street, Mitchell, South Dakota ("Mitchell Facility"), within the jurisdiction of this Court.

5. Charles L. Voellinger, Sr. owns Dakota Laboratories. Voellinger is also the owner and President of Nomax, Inc., the parent company of Dakota Laboratories. He has final responsibility over all of Dakota Laboratories' operations including but not limited to the manufacture, processing, packing, labeling, holding, and distribution of drugs at and from the Mitchell Facility. He has the authority to institute company procedures including procedures related to manufacturing and quality control. Although Voellinger typically performs his duties from Nomax offices, in St. Louis, Missouri, he occasionally travels to the Mitchell Facility to perform his oversight activities, within the jurisdiction of this Court.

6. Defendants have been engaged in manufacturing, processing, packing, labeling, holding, and distributing sterile eye drops, which are articles of drug within the meaning of 21 U.S.C. § 321(g).

7. Defendants manufacture sterile eye drops using components that have been shipped to them in interstate commerce from locations including California, and distribute their products outside of South Dakota by shipping finished products to Dakota Laboratories' parent company in St. Louis, Missouri, for further distribution.

Adulterated Drugs

8. FDA's inspections of the Mitchell Facility have established that the sterile eye drops manufactured by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) in that the methods, facilities, and controls used for their manufacture, processing, packing, and holding do not conform to CGMP requirements. Compliance with CGMP requirements assures that articles of drug meet the safety requirements of the Act and have the identity, strength, quality, and purity that the articles purport to possess. FDA regulations, which establish the minimum CGMP requirements applicable to human drugs, require manufacturers to control all aspects of the processes and procedures by which drugs are manufactured to prevent the production of unsafe and ineffective products. 21 C.F.R. Parts 210 and 211. Drugs not manufactured, processed, packed, and held in conformance with CGMP are deemed to be adulterated as a matter of law, without any showing of actual defect.

9. FDA conducted three inspections of the Mitchell Facility since 2010. During each inspection, FDA investigators documented significant deviations from CGMP in the processes and conditions in which Defendants manufacture sterile eye drops. Based on the seriousness of the findings in 2010, FDA issued a Warning Letter to Defendants that described their CGMP violations and noted the inadequacies of their written response to the 2010 inspectional observations. FDA's inspection in 2011 confirmed that Defendants continued to manufacture sterile eye drops in violation of CGMP requirements. A follow-up inspection by FDA in 2012 documented that Defendants have not adequately remedied the CGMP deficiencies in their manufacturing operations. Defendants' CGMP violations are so systemic and pervasive that there is little assurance that their eye drops are what they purport to be, i.e., sterile.

10. FDA's inspection conducted on April 2–5, 2012, documented that:

A. Defendants fail to establish and implement appropriate procedures (including validation protocols) for preventing microbiological contamination of drug products that purport to be sterile, as required by 21 C.F.R. § 211.113(b). For example:

(1) Defendants have not conducted adequate validation studies to show that their process for transferring ("filling") eye drops into retail bottles is adequately designed to prevent the products from becoming contaminated with bacteria. Defendants deviated from their validation protocol by omitting a required annual test to simulate filling eye drops into retail bottles at a slow speed, which extends the time to complete the filling process.

(2) Defendants have not completed their validation studies for their re-use of the .2 micron filter for purifying water used to manufacture eye drops. Defendants allow their employees to re-use the filter up to 10 times, even though Defendants completed only one of the five simulation tests required by their protocol to validate filter re-use.

(3) Defendants have not developed a protocol for maintaining and sanitizing their new water purification system or established the appropriate frequency for maintenance and sanitization, even though they use the water from the new system to manufacture eye drops.

B. Defendants fail to investigate discrepancies, as required by 21 C.F.R. § 211.192. For example, Defendants did not investigate their employees' use of expired materials for testing the chlorine level in the water used to manufacture eye drops.

C. Defendants lack sufficient control over the environment in their sterile-processing area to prevent products from becoming contaminated during sterile processing, as required by 21 C.F.R. § 211.42(c)(10). For example, Defendants have not established that the quality of the air maintained in their sterile-processing suite is adequate to prevent eye drops from becoming

contaminated with bacteria during processing. Specifically, Defendants failed to conduct studies to determine the amount of time necessary for the main HEPA air filters to recover the air quality in the sterile-processing suite once the filters are switched on again after they have been switched off when the suite is not in use.

D. Defendants fail to establish and implement appropriate laboratory procedures for determining whether batches of eye drops conform to their specifications, as required by 21 C.F.R. § 211.165. For example, Defendants have not conducted adequate validation studies to establish the accuracy and reliability of their sterility tests. In evaluating a new sterility-testing system for verifying the sterility of eye drops before filling them into retail bottles, Defendants deviated from their validation protocol by omitting a required volumetric measurement during the simulation test.

11. FDA's inspection conducted on August 8–11, 16–18, and 29–31, 2011, documented that:

A. Defendants fail to establish and implement appropriate procedures (including validation protocols) for preventing microbiological contamination of drug products that purport to be sterile, as required by 21 C.F.R. § 211.113(b). For example:

(1) Defendants did not validate their process for filling eye drops into retail bottles to show that it was adequately designed to prevent the products from becoming contaminated with bacteria. Specifically, Defendants' simulation test did not reflect their actual manufacturing operations and did not comply with their validation protocol. Defendants' records documented an instance where an actual filling time spanned 2 days, which was significantly longer than the filling time of their simulation run (3.25 hours) or the filling time

required by their protocol (5 hours). In addition, Defendants did not account for the disposition of 131 bottles that had been filled during the simulation test.

(2) Defendants relied on a .2 micron filter to sterilize their eye drops without showing that the filter had the filtering capacity to remove bacteria from the eye drops, which occasionally tested high for bacteria at the pre-filtration stage. Defendants also failed to set a limit on the number of times a sterilizing filter could be re-used and re-sterilized in the autoclave, even though the firm was using and autoclaving the filters up to eleven times. In addition, Defendants used the sterilizing filter before completing simulation tests to show that, based on the manner in which they used the autoclave (e.g., the number of filters per autoclave cycle), the autoclave was able to render the filters sterile.

(3) Defendants relied on a .2 micron filter to purify the water used to manufacture their eye drops without showing that the filter was effective in reducing the level of bacteria in the water, which occasionally tested above the firm's "action limit" for bacteria. In addition, on several occasions Defendants failed to conduct an investigation when the pre-filtered water exceeded the bacterial action-limit. Based on this inspectional observation, Defendants fail to comply with the requirements in 21 C.F.R. §§ 211.113 and 211.192.

B. Defendants fail to investigate discrepancies, as required by 21 C.F.R. § 211.192. For example, Defendants did not conduct an investigation after discovering that one of the HEPA air filters in the sterile-processing suite failed a leak test. Based on this inspectional observation, Defendants also fail to comply with the requirements in 21 C.F.R. § 211.42(c)(10).

C. Defendants lack sufficient control over the environment in their sterile-processing area to prevent products from becoming contaminated during sterile processing, as required by 21 C.F.R. § 211.42(c)(10). For example, Defendants failed to monitor the environment in their

sterile-processing suite during manufacturing. After filling one batch of eye drops into retail bottles, Defendants waited over two days to conduct environmental testing in the sterile-processing suite.

D. Defendants fail to adhere to their established laboratory-control mechanisms, as required by 21 C.F.R. §§ 211.160 and 211.165. For example, Defendants incubated samples for microbial testing in an incubator that exceeded the upper temperature limit for those samples.

12. FDA's inspection conducted on June 22–24, 2010, documented that:

A. Defendants fail to establish and implement appropriate procedures (including validation protocols) for preventing microbiological contamination of drug products that purport to be sterile, as required by 21 C.F.R. § 211.113(b). For example:

(1) Defendants manufactured and distributed several batches of eye drops without completing the simulation testing to validate their manufacturing process, i.e., they failed to show that their process for filling the eye drops into retail bottles was adequately designed to prevent the products from becoming contaminated with bacteria.

(2) Defendants relied on a .22 micron filter to sterilize their eye drops without establishing any specifications for the filter to show that it had the filtering capacity to remove bacteria.

(3) Defendants manufactured two batches of eye drops with purified city water, which they purified on-site, without conducting microbial testing to verify its purity.

(4) Defendants manufactured two batches of eye drops with bulk concentrates that had been held in a refrigerator 2.5 to 3 times longer than the firm's established hold times, without investigating whether the hold-time deviations increased the risk of bacterial contamination. In addition, Defendants had no scientific basis to justify their established hold

times for any of the bulk concentrates they used in manufacturing eye drops. Based on this inspectional observation, Defendants fail to comply with the requirements in 21 C.F.R. §§ 211.111, 211.113(b), and 211.192.

B. Defendants fail to investigate discrepancies, as required by 21 C.F.R. § 211.192. For example, Defendants manufactured batches of eye drops in their sterile-processing suite, even though environmental testing showed the area exceeded the firm's established bacterial limits. They failed to investigate whether the deviations in bacterial levels increased the risk of contamination.

C. Defendants lack sufficient control over the environment in their sterile-processing area to prevent products from becoming contaminated during sterile processing, as required by 21 C.F.R. § 211.42(c)(10). For example, Defendants did not have a written standard operating procedure for environmental monitoring of their sterile-processing area.

13. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), as set forth above.

14. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to be adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) after shipment of one or more of their components in interstate commerce, as set forth above.

Prior Warnings

15. Defendants' noncompliance has continued despite repeated warnings from FDA regarding their CGMP violations. At the conclusion of each FDA inspection, the FDA investigator(s) prepared and issued a detailed List of Inspectional Observations (Form FDA-483) to Dakota Laboratories' management and discussed the inspectional findings with them.

16. FDA also issued a Warning Letter to Charles L. Voellinger, Sr. on March 17, 2011, based on the findings of FDA's 2010 inspection. The Warning Letter emphasized the serious nature of the CGMP violations at the Mitchell Facility and stated that a failure to correct the violations could lead to regulatory action including an injunction.

17. Defendants responded to the Forms FDA-483 from all three inspections and to the Warning Letter. In their responses, Defendants attempted to justify their failure to follow their own procedures, promised improvements, or submitted information purporting to show that corrective actions were taken. As FDA investigators documented during subsequent inspections, Defendants' promises have not been kept, and their attempts to remedy their CGMP deficiencies have been wholly inadequate.

18. Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. §§ 331(a) and (k), in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin Defendants Dakota Laboratories, LLC, Charles L. Voellinger, Sr., and each and all of their officers, agents, employees, attorneys, successors, and assigns, and all persons in active concert or participation with any of them, pursuant to 21 U.S.C. § 332(a), from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

B. Violating 21 U.S.C. § 331(k) by causing drugs to be adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) while the drugs are held for sale after shipment of one or more of their components in interstate commerce;

II. Permanently restrain and enjoin Defendants Dakota Laboratories, LLC, Charles L. Voellinger, Sr., and each and all of their officers, agents, employees, attorneys, successors, and assigns, and all persons in active concert or participation with any of them, from manufacturing, processing, packing, labeling, holding, or distributing articles of drug, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute articles of drug are established, operated, and administered in conformity with CGMP requirements and the Act, in a manner that has been found acceptable by FDA;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be awarded costs and such other equitable relief as the Court deems just and proper.

DATED this 23rd day of August, 2013.

Respectfully submitted,

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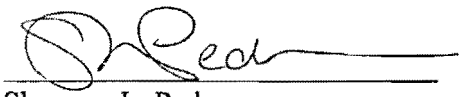

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